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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 08/459,141
Filing Date: June 02, 1995
Appellant(s): BERMAN ET AL.

Emily M. Haliday
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 27, 2004 appealing from the Office action mailed December 16, 2002.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

08/471,107

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Berman et al. U.S. Patent No. 4,855,224

Watson et al. Herpes simplex virus type-1 glycoprotein gene: nucleotide sequence and expression in E. coli. Science (1982) Vol. 218, pages 381-384.

Dundarov et al. Immunotherapy with inactivated polyvalent herpes vaccines. Developmental Biological Standards (1982) Vol. 52, pages. 351-358.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 10-12, 14-19, 25-29, 32-41 are rejected under the judicially created doctrine of double patenting over claims 13, 19 and 20 of U. S. Patent No. 4,855,224 since the claims, if allowed, would improperly extend the "right to exclude" of the composition already patented in the prior application. Upon further reconsideration the following claims 1-5, 9, 21, 25, 26 from the '224 patent are added to the double patenting rejection.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claims of the instant application are drawn to an immunogenic composition that is devoid of a membrane-binding domain. The claims are interpreted to be product-by-process claims and therefore are interpreted as "a composition of matter" (which are products). Product-by- process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made

> by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

The patented claims are drawn to diagnostic products, which have the same structure as the instantly claimed immunogenic composition. The diagnostic product is a truncated membrane-free derivative of a polypeptide (comprising the first 300 amino acids), wherein the polypeptide is devoid of membrane binding domain and is free of membrane. The cell line expressing the product contains a plasmid (made of nucleic acids) with a selectable dhfr marker (see figure 8). Chemical compounds and their properties are inseparable, therefore, the limitation does not distinguish the instant invention over the prior art. See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). The instantly claimed immunogenic composition comprises the same structure as the patented diagnostic product. Therefore, the instant invention is obvious in view of the patented claims of '224.

MPEP 804 provides that the specification can be consulted when making an obvious type double patenting rejection.

> MPEP 804: When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure. The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a

> reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

In the instant rejection, the structure of the prior patented "diagnostic product" is the same as that in the present invention, adding descriptive phrase "capable of raising neutralizing antibodies *in vivo*" does not alter the structure of the composition. Because antibodies recognize structure, the '224 patented diagnostic structure is the same as the presently claimed immunogenic structure and therefore meets the limitation of "capable of raising neutralizing antibodies *in vivo.*" These diagnostic structures produced using the claimed recombinant cells of '224 "posses a number of antigenic determinants in common with the native virus." (see '224, column 16, lines 15-16). The gD product of the claimed recombinant cell has at least one antigenic determinant that is known to be a neutralize g antigenic determinant (see '224, column 16, lines 15-24).

The diagnostic products of the '224 patent are derived from stable continuous cell lines capable of the production of the diagnostic products. Looking to the '244 patent for the description of the cell line producing the truncated diagnostic product. (see column 17, line 65 to column 18, line 4).

> The expression plasmid consisted of the pBR322 bacterial origin of replication and ampicillin resistance gene, a cDNA insert encoding the murine dihydrofolate reductase gene under the transcriptional control of the SV40 early promoter (53) and a HindIII-Hindf1 fragment which encodes the first 300 amino acids of gD under the transcriptional control of a second Sv40 early promoter. The HindIII site of this fragment lies 74 bp to the 5' side of the initiator methionine of the gD gene. The HindIII site of the SV-40 early region vector (36) lies 250 bp to the 3' side of the Goldberg-Hogness box of the SV40 promoter. The Hinf1 site (blunted with Klenow DNA polymerase and 4 deoxynucleotide triphosphates) is ligated to the Hpa1 site of the 3' nontranslated region of the hepatitis B virus surface antigen gene (36). This method is also useful for preparing a truncated HSV-2 gene.

> (see column 19, lines 37-44) The resulting vector was transfected (40) into a dhfr.sup.-CHO cell line (39), and a suitable clone gG10.2 selected which produced the truncated gD protein and secreted it into the surrounding medium. The protein was extracted from the medium and the cells were tested for immunogenic activity. FIG. 9 shows the results of immunoprecipitations of intra- and extra-cellular.sup.35 S-methionine-labelled extracts.

Proteins are encoded by nucleic acids and cell lines that are capable of expressing the diagnostic product by virtue of being cells will inherently possess the nucleic acids that encode the diagnostic product. The instantly claimed invention is claimed using open claim language "an immunogenic composition comprising."

> MPEP 2111.03 The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS*, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

The mere recitation of newly-discovered function (capable of raising neutralizing antibodies) or property, inherently possessed by things in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977), *In re Schreiber* 44 USPQ2d 1429). *In re Best* is directed to a particular set of circumstances where examiners in the USPTO cannot readily determine whether a difference exists between the subject matter of a given claim and a particular prior art document. Typically these circumstances arise in the context of a claim directed to a compound or composition where the claim describes a property or a function of the compound or

composition which the prior art reference does not address, as in the present situation. As explained in *In re Best*, if the claimed and prior art products are identical or substantially identical, the USPTO can require an applicant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. In order to invoke the principles of *In re Best,* the examiner must first make factual findings which support the conclusion that the claimed and prior art products *prima facie* are "identical or substantially identical." That determination must be made case-by-case based upon the facts in the individual case. The instantly claimed immunogenic composition and the patented diagnostic product were made using the same cell line, thus the product produced from the cell line would be expected to have the same structure. Products with the same structure are anticipated to have the same function.

Claims 10-23 and 25-41 are rejected under the judicially created doctrine of double patenting over claims 13, 19 and 20 of U. S. Patent No. 4,855,224 in view of Watson et al (Science 1982) and Dundarov et al. (Dev Biol Stand. 1982). Upon further reconsideration the following claims 1-5, 9, 21, 25, 26 from the '224 patent are added to the double patenting rejection.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The claims of the instant application are drawn to an immunogenic composition that is devoid of a membrane-binding domain. The claims are interpreted to be product-by- process

claims and therefore are interpreted as "a composition of matter" (which are products). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps.

Looking to the specification for a detailed description of the cell line which is capable of producing the truncated diagnostic product (see column 17, line 65 to column 18, line 4; and column 19, lines 37-44), it is found that the patented claims drawn to the diagnostic product, have the same structure as the instantly claimed immunogenic composition. The diagnostic product is a truncated membrane-free derivative of a polypeptide (comprising the first 300 amino acids), wherein the polypeptide is devoid of membrane binding domain and is free of membrane. The cell line expressing the product contains a plasmid with a selectable dhfr marker (see figure 8). Chemical compounds and their properties are inseparable; therefore, the limitation does not distinguish instant invention over the prior art. See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The patented claims do not teach HSV gB. However, the production of an HSV gB immunogenic composition would be obvious over the patented claims in view of Watson et al. The reference teaches that HSV glycoproteins A-E are known and that antibodies to all of the glycoproteins are capable of neutralizing infection (see Watson column 1, 2nd paragraph). Following the procedure provided in the patent and knowing that HSV glycoproteins A-E can stimulate neutralizing antibodies, the production of neutralizing antibodies to HSV gB are obvious.

The patented claims also do not teach a polyvalent mixture of the immunogenic compositions. A polyvalent combination of multiple HSV glycoproteins would be obvious to the

ordinary artisan. Watson et al. that teaches that neutralizing antibodies are made to all HSV glycoproteins and Dundarov et al. teaches the production of a polyvalnet whole virus vaccine. The. polyvalnet vaccine of Dundarov et al comprises five different strains of HSV-1 and five different strains of HSV-2, thereby taching the use of a polyvalent mixture comprising HSV glycoproteins. The instant invention drawn to an immunogenic composition comprising HSV gB, gC and gD and combinations thereof (polyvalent) and a cell line cable of producing the individual components of the immunogenic composition is obvious over '224 in view of Watson et al. and Dundarov et al.

The structure of the prior patent '224 is the same as the structure claimed in the present invention, adding a mere descriptive phrase "capable of raising neutralizing antibodies *in vivo*" does not alter the structure of the composition. Because antibodies recognize structure, the prior patent structure is the same as the present structure and therefore meets the limitation of "capable of raising neutralizing antibodies *in vivo*."

The diagnostic products of the '224 patent are derived from stable continuous cell lines capable of the production of the diagnostic products. Proteins are encoded by nucleic acids and cell lines that are capable of expressing the diagnostic product by virtue of being cells will inherently possess the nucleic acids that encode the diagnostic product. The instantly claimed invention is claimed using open claim language "an immunogenic composition comprising."

> MPEP 2111.03 The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS*, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA

1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

The mere recitation of newly discovered function (capable of raising neutralizing antibodies) or property, inherently possessed by things in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977), *In re Schreiber* 44 USPQ2d 1429). *In re Best* is directed to a particular set of circumstances where examiners in the USPTO cannot readily determine whether a difference exists between the subject matter of a given claim and a particular prior art document. Typically these circumstances arise in the context of a claim directed to a compound or composition where the claim describes a property or a function of the compound or composition which the prior art reference does not address, as in the present situation. As explained in *In re Best*, if the claimed and prior art products are identical or substantially identical, the USPTO can require an applicant to prove that the prior art product does not necessarily or inherently possess the characteristics of the claimed product. In order to invoke the principles of *In re Best,* the examiner must first make factual findings which support the conclusion that the claimed and prior art products *prima facie* are "identical or substantially identical." That determination must be made case-by-case based upon the facts in the individual case. The instantly claimed immunogenic composition and the patented diagnostic product were made using the same cell line, thus the product produced from the cell line would be expected to have the same structure. Products with the same structure are anticipated to have the same function.

(10) Response to Argument

Appellants' argument is that the instant invention is claiming a structural-functional element that is not present in the prior U.S. Patent No. 4,855,224. "Specifically, the pending claims recite "a truncated membrane-free derivative of a polypeptide...[that] has exposed antigenic determinants capable of raising neutralizing antibodies against *in vivo* challenge by the pathogen." (see claim 10). Appellants argue that the conclusion derived by the Office improperly relied on the specification of the U.S. Patent No. 4,855,224 and did not limit the comparison to the claims only.

Appellants' argument is not convincing. It is always proper to use the specification as a dictionary to define the meaning of the terms in a claim (*In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). The following is a side-by-side comparison of the patented product and the instantly claimed immunogenic structure.

US Pat. No. 4,855,224 Claims 13 and 19	The broadest claim of the instant specification is claim 10.
Claim 13: A diagnostic kit comprising: (a) a diagnostic product comprising a membrane bound polypeptide with **antigenic determinants** capable of specifically binding complimentary antibodies to herpes simplex virus, said polypeptide being formed in a recombinant, stable continuous cell line; and (b) a second component comprising either said complementary antibody or anti-antibody capable of specifically binding said complementary antibody. Claim 19: The diagnostic test kit of claim 13 in which said diagnostic **product is a truncated, membrane-free derivative of a polypeptide, said derivative being devoid of a membrane binding domain whereby the**	Claims 10: An immunogenic composition comprising **a truncated, membrane free derivative of a polypeptide** comprising a membrane binding domain and **antigenic determinates** capable of raising neutralizing antibodies against in vivo challenge by a pathogen wherein said derivative: (a) is **devoid of membrane binding domain whereby the derivative is free of membrane**, and (b) has exposed antigenic determinates capable of raising neutralizing antibodies against in vivo challenge by the pathogen.

derivative is free of said membrane.	

The patent '224 claims are arranged as an independent/dependent claims 13 and 19 combination. A dependent claim is construed to contain all the limitations of the claim upon which it depends in addition to any limitation presented in the dependent claim. In '224 claim 13 was directed to a membrane bound polypeptide that was made using a recombinant stable continuous cell line. Claim 19 added the additional limitation that the diagnostic product is produced by the recombinant stable cell line but that the polypeptide is not membrane bound (membrane free derivative) because it is devoid of the membrane binding domain. The instantly claimed composition comprises a pathogen derived polypeptide, that is devoid of the membrane binding domain (truncated). This membrane free derivative composition can be used to elicit an immunogenic response. Because the composition requires the presence of at least one antigenic determinant that can elicit an antibody response in an animal the ordinary artisan would know that the polypeptide must be greater than six amino acids in length. The minimum size of a peptide that can elicit an immune response is six amino acids, there is no maximum size limit but the ordinary artisan would know that larger proteins have more epitopes. The instant claims are broadly drawn to a pathogen derived protein (genus) and pathogens includes herpes simplex virus proteins (species). Proteins are chemicals and the function of the protein cannot be separated from the structure of the protein [In re Best, *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977)]. Thus the limitation that the protein has exposed antigenic determinates capable of raising neutralizing antibodies against *in vivo* challenge by the pathogen is a function of the protein and does not add any structural elements to the composition. Because the instant claims use open claim language the composition can include additional elements even in large amounts as long as the additional do not affect the structure of the composition. Therefore, the

immunogenic composition can read on a whole cell composition expressing the product of interest and can include any other components.

Without consulting the specification of US Pat. No. 4,855,224 the following is known about the patented composition. The composition comprises a membrane free derivative of a polypeptide, the polypeptide must be from a herpes simplex virus because antibodies that recognize herpes simplex virus protein (complementary antibodies) recognize the membrane free derivative composition. That the composition is part of a diagnostic kit just means that the composition comprises additional elements. The additional element, the secondary antibody, will not affect the antigenic character of the diagnostic product.

It is proper to look to the patented specification of the '224 to determine the structure that is encompassed by the claimed invention.

In order to make a meaningful comparison between the patented subject matter and the instantly claimed subject matter, the examples that are encompassed by the claimed invention may be examined for their similarity to determine the structural differences between the patented subject matter and the instantly claimed subject matter. "The specification can always be used as a dictionary to learn the meaning of a term in the patent claim." *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). The term "diagnostic product" and the "fragment of a glycoprotein" needed to be looked up in the specification in order to understand the structure of the claimed invention in '224. In order to understand the term "devoid of membrane-binding domain" the meaning also needed to be looked up in the specification. The ordinary artisan would recognize that the removal of a membrane binding domain (devoid of membrane binding

domain) can be achieved either through an enzymatic digestion of a surface protein or by recombinant technology in which the membrane spanning domain is excised form the nucleic acid structure that expresses the protein. Thus it is necessary to consult the specification to determine which of the two possible processes are contemplated by the term.

> *In re Vogel*, 422 F2d 438, 164 USPQ 619, at 622 (CCPA 1970)
>
> A claim is a group of words defining only the boundry of the patent monopoly. It may not describe any physical thing and indeed may encompass physical things not yet dreamed of. How can it be obvious or not obvious to modify a legal boundary? The disclosure, however, sets forth at least one tangible embodiment within the claim, and is less difficult and more meaningful to judge whether that thing has been modified in an obvious manner. It must be noted that this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 USC 103, since only the disclosure of the invention claimed in the patent may be examined.

Thus *In re Vogel* allows the inspection of the patented specification in order to determine the structure of at least one tangible embodiment that falls within the patented claim. This portion of the specification is not considered prior art. It is easier to compare a tangible embodiment. The tangible embodiment that "comprises a membrane free derivative of the polypeptide" of the '244 patent is found in example 1, 2 and 3 of '244. Examples 1, 2 and 3 sets out the cloning of gD genes of HSV1 and HSV2, the establishment of a permanent membrane-bound gD producing cell line, and the use of a selectable marker dhfr in the production of the cell line. Furthermore, example 3 discloses production of a polypeptide gD comprising a fragment of the membrane bound polypeptide by removing of the membrane-spanning domain in the nucleic acid used for expressing the protein in the cell line.

The function of a composition is an inherent feature of the structure.

It is well settled patent law that an old composition does not become patentable upon the discovery of a new property of that composition. See MPEP 2112.

> "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195USPQ 430, 433 (CCPA 1977).

Antibodies recognize epitopes (structures) that are present in proteins or chemicals. A protein will have epitopes (which are a property of the structure) and an epitope has two functions in a body. One function of an epitope is to elicit antibody production this occurs in when the protein is injected into a naïve animal, the animal will produce antibodies to the new epitopes. The second function to restimulate the immune system, this occurs if an animal has already been exposed to the protein it will be possess antibodies and antibody producing cells that are able to recognize the epitopes. Thus, depending on the immunogenic state of the animal, the same epitopes will either function to elicit an antibody response in a naïve animal, or to stimulate a secondary antibody response in an animal that has seen the epitope before. The epitope (protein) can also be used to determine whether an animal has seen the protein before by using the protein to determine whether the animal recognizes the epitope by looking for antibodies to the epitope. This is the use (diagnostic) for the composition claimed in the '224 patent. Thus the previously patent structure (composition) comprises epitopes that can be used to elicit an antibody response in an animal or the structure can be used to detect (diagnostic) whether an animal possess antibodies to the structure. The argument that the '224 product is

used as a diagnostic is not convincing because the structure of the product is not changed when it is used as an immunogen. The product structure remains the same. *In re Vogel* allows the inspection of the patented specification in order to determine the structure of at least one tangible embodiment that falls within the patented claim. Thus, it is permissible to look at the examples to determine how the membrane-free derivative is made. Since the patented membrane-free derivative is made from the same cell line as the instantly claimed immunogenic composition, the structure must have the same function. *In re Best*, 562 F.2d 1252, 1254, 195USPQ 430, 433 (CCPA 1977).

No modification of the diagnostic kit of '244 is required to arrive at the claimed invention.

Applicant argues that the '224 claims 13, 19 and 20 recite a diagnostic kit rather than a polypeptide derivative. Claim 19 reads as follows:

> ('224) Claim 19: The diagnostic test kit of claim 13 in which said diagnostic product is a truncated, **membrane-free derivative of a polypeptide**, said derivative being devoid of a membrane binding domain whereby the derivative is free of said membrane.

Thus the argument that the kit is not limited to a polypeptide derivative is not convincing because the instantly claimed invention by virtue of using the term "comprising" can include additional elements in conjunction to polypeptide derivative. The '224 kit has additional components such as a secondary antibody. When injecting an animal with the diagnostic product of '224 which includes the secondary antibody, the animal is expected to elicit an immune response to the peptide derivative and to the secondary antibody. An immune response to both components does not affect the structure of the diagnostic product, and is does not prevent the diagnostic product from eliciting a neutralizing or complementary immune response. *In re Vogel*

allows the inspection of the patented specification in order to determine the structure of at least one tangible embodiment that falls within the patented claim. Thus, it is permissible to look the examples to determine how the membrane-free derivative is made. It is also permissible to look at the instant specification to determine how the membrane-free derivative of the instantly claimed composition is made, because this example is a tangle structure that falls within the claim scope. Since both the diagnostic product and the instantly claimed membrane-free derivative are made form the same cell lines the ordinary artisan could only conclude that they are the same structure. Products that have the same structure have the same function. *In re Best*, 562 F.2d 1252, 1254, 195USPQ 430, 433 (CCPA 1977).

Obvious type double patenting based on the inherent structure of the composition is proper.

"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 125 USPQ 345 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). *In re Vogel* allows the inspection of the patented specification in order to determine the structure of at least one tangible embodiment that falls within the patented claim. Thus, it is permissible to look example 3 to determine how the membrane-free derivative is made. Since both the diagnostic product and the instantly claimed membrane-free derivative are made form the same cell lines the ordinary artisan could only conclude that the same cell lines will produce the same structure. Products that have the same structure have the same function. *In re Best*, 562 F.2d 1252, 1254, 195USPQ 430, 433 (CCPA 1977).

It is permissible to look at the specification for purposes of determining at least one structure that falls within the claim of '224. The comparison between the patent and the instant specification yields that the same cell lines are used for the production of a single embodiment the HSV gD glycoprotein derivative and thus would produce derivatives having the same structure. Without looking to the specification it was known (Watson et al.) that the herpes glycoproteins gA, gB, gC, gD, and gE are able to elicit neutralizing immune responses in an animal. "Antiserums to each of these glycoproteins can neutralize infectivity of the homologous HSV type in an in vitro assay." (see Watson et al. , page 381, column 1, paragraph 2). Thus the modification of the prior patented diagnostic product would be obvious because the prior art had established that patients produce neutralizing antibodies to all of the HSV glycoproteins, therefore, any HSV glycoprotein would be an obvious diagnostic.

Claim 12 is not separately patentable.

Claim 12 of the instant invention recites the composition that is a derivative of polypeptide C. Although, the specification of the '224 patent only discloses the production of the membrane-free derivative of the HSV gD polypeptide, the '224 patented claims are not limited to polypeptide D. Furthermore, claims 1 and 4 of the '224 patent specifically claim a fragment of polypeptide C. The only fragments disclosed the patent are the membrane-free derivative fragments, thus the fragment of claim 4 of '224 would encompass a membrane free derivative. Without looking to the specification it was known (Watson et al.) that the herpes glycoproteins gA, gB, gC, gD, and gE are able to elicit neutralizing immune responses in an animal. "Antiserums to each of these glycoproteins can neutralize infectivity of the homologous

HSV type in an in vitro assay." (see Watson et al. , page 381, column 1, paragraph 2). It would have been obvious to formulate a polyvalent vaccine because it was known that all HSV glycoproteins elicit a neutralizing antibody response.

The obvious double patenting rejection in view of Watson or Dundarov is proper.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Watson et al. established that neutralizing antibodies can be made to all of the HSV glycoprotein. While the Dundarov et al. reference teaches the use of polyvalent whole virus vaccines as a method of immunizing. The '224 patent claims are broadly directed to a truncated membrane free derivative of a herpes simplex virus that is able to bind complementary antibodies. The '224 claims contemplate all herpes virus glycoproteins. There is nothing in the art that would suggest that the other herpes virus glycoproteins would behave differently.

Applicants cite *In re Rijckaert*, 9 F.3d 1531, 28 USPQ 2d 1955 (Fed. Cir. 1993) for the proposition that "obviousness cannot be predicated onto what is unknown." Applicants argument that the inherent property attributed to the disclosed example of the truncated gD can not be extrapolated to gB is gC is not convincing because Watson et al. has established that glycoprotein A-E are similarly embedded into the virion envelope and have similar structure.

Waston et al. also indicated that antiserums to each of the glycoproteins can neutralize infectivity of the homologous HSV type. (see Watson et al. , page 381, column 1, paragraph 2). Therefore, there is nothing in the prior art that would indicate only the gD structure exemplified in the '224 patent would be capable of producing neutralizing antibodies while the other glycoprotein could not produce neutralizing antibodies.

In this instance the patented '224 claims are broadly drawn to all membrane free derivatives of herpes simplex viruses glycoproteins. The claims are not limited to the single HSV gD structure that is specifically exemplified in '224. Thus in order to establish obviousness the question is what other glycoproteins of HSV are known at the time the invention was filed? Waston et al. established that HSV glycoproteins A-E were known at the time the instant invention was filed. These glycoproteins were also known at that time to produce neutralizing antibodies. Thus, membrane-free derivatives of all known glycoproteins are obvious because the '224 claims are broadly drawn to all membrane-free derivatives of HSV glycoproteins.

In order to establish obviousness for a polyvalent mixture of the glycoproteins the next question is what immunogens would be effective? Dunderov et al. established that at the time of the invention was filed it was known to make polyvalent vaccine composition to establish protection against a broader group of herpes pathogens. In Dunderov et al. several viral strain were combined indicating that the composition comprises all viral glycoproteins from several stains of HSV. Because the reference established that the polyvalent vaccine appears to be effective this would indicate that producing a composition with more than one glycoprotein would also be effective. There is no indication in the art that using more than one glycoprotein would produce interfering antibodies making the composition of more than one glycoprotein

undesirable. Therefore, combining more than one glycoprotein for the purpose of making an immunogenic composition would be obvious.

An obviousness type double patenting rejection does differ somewhat from a 103 obviousness rejection. An obvious type double patenting rejection is made in situations when the claim language between the patented claims differ form the claims under consideration this is the case here. The obvious type double patenting rejection is made when the claims anticipate the invention yet the claim language describing the invention differs. In the claims under consideration in the instant application the claim language is differs from the patent claims. By looking at the exemplified embodiments the structures of the '224 claims are found to the same (anticipation) as the instantly claimed stuctures. It is well settled patent law that products that have the same structure have the same function. *In re Best*, 562 F.2d 1252, 1254, 195USPQ 430, 433 (CCPA 1977). The '224 patented claims more structures than those exemplified in the '224 specification and thus the additional references merely serve to show that using other glycoproteins of HSV would be obvious.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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